IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	:	10/645293	Confirmation No. 7202
Applicant	:	John R. Peery	
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Art Unit	:	1618	
Examiner	:	Ebrahim, Nabila G	
Docket No.	:	ARC2437USCON6	
Customer No.	:	30766	
Title	:	Sustained Delivery of an Active Agent Using an Implantable System	

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Commissioner for Patents
P. O. Box 1450
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AMENDMENT

Sir:

In response to the Office Action dated June 14, 2007, kindly amend the application identified above as follows:

AMENDMENTS TO THE CLAIMS are reflected in the listing of claims which begins on page 2 of this paper.

REMARKS/ARGUMENTS begin on page 7 of this paper.

AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions, and listings, of claims in the application:

LISTING OF CLAIMS

1-50. (Canceled)

51. (Currently Amended) An implantable device for delivering an active agent to a fluid environment of use, said device comprising a reservoir and a back diffusion regulating outlet for delivering fluid from the reservoir to the fluid environment, the reservoir and back diffusion regulating outlet having surfaces in a mating relationship, wherein a helical flow path is formed between the mating surfaces, wherein ~~the outlet has a helical flow path selected so that~~ a length of the helical flow path is sufficient to prevent back-diffusion of external fluid through the helical flow path, wherein the helical flow path has a length of about 2 to about 7 cm.

52. (Currently Amended) An implantable device for delivering an active agent to a fluid environment of use, said device comprising a reservoir and a back diffusion regulating outlet for delivering fluid from the reservoir to the fluid environment, the reservoir and back diffusion regulating outlet having surfaces in a mating relationship, wherein a helical flow path is formed between the mating surfaces, wherein ~~the outlet has a helical flow path selected so that~~ a length of the helical flow path is sufficient to prevent back-diffusion of external fluid through the helical flow path, wherein the helical flow path has a diameter of about 0.003 to about 0.020 inches.

53. (Previously Presented) The device of claim 52, wherein the helical flow path has a length of about 2 to about 7 cm.

54. (Currently Amended) The device of claim 51, wherein the back diffusion regulating outlet comprises a thermoplastic member and the reservoir comprises a metal capsule and the helical flow path is formed by a helical groove in an exterior of ~~a~~ the thermoplastic member and by an interior of ~~a~~ the metal capsule.

55. (Currently Amended) A fluid-imbibing device for delivering an active agent to a fluid environment of use, said device comprising a water-swellable semipermeable ~~material~~ plug that is received in sealing relationship with an interior of the surface of an open end of an implantable reservoir and an active agent to be displaced from the device when the water-swellable ~~material~~ semipermeable plug swells, wherein an exterior surface of the semipermeable ~~material~~ plug includes circumferential ridges.

56. (Currently Amended) The device of claim 55, wherein the semipermeable ~~material~~ plug seals to the interior surface of the open end such that the semipermeable ~~material~~ plug is retained in the open end.

57. (Previously Presented) The device of claim 71, wherein the semipermeable material includes circumferential ridges.

58. (Currently Amended) The device of claim 57, wherein ~~the semipermeable material ridges provide~~ there is a clearance between the ridges and ~~an~~ the interior surface of the reservoir into which the semipermeable material expands due to hydration.

59. (Currently Amended) The device of claim 55, wherein the semipermeable ~~material~~ plug is ~~a~~ substantially cylindrical ~~plug which~~ and expands radially upon hydration to provide a friction fit with the interior surface and ~~expands~~ longitudinally to displace the active agent.

60. (Currently Amended) The device of claim 55, wherein the semipermeable plug comprises a material ~~is~~ selected from the group consisting of plasticized cellulosic materials, polyurethanes, and polyamides.

61. (Currently Amended) A fluid-imbibing device for delivering an active agent to a fluid environment of use, said device comprising:

an impermeable reservoir having an interior surface and an open end;

a water-swellable, semipermeable, substantially cylindrical plug received in sealing relationship with the interior surface of the impermeable reservoir at the open end, wherein an exterior surface of the plug ~~having~~ has a plurality of circumferential ridges; and

an active agent received in the reservoir to be displaced from the reservoir by passage of fluid through the plug.

62. (Currently Amended) The device of claim 61, wherein ~~the circumferential seals provide~~ there is a clearance between the ~~seals~~ circumferential ridges and the interior surface of the reservoir into which the plug expands due to hydration.

63. (Previously Presented) The device of claim 61, wherein the plug comprises a material selected from the group consisting of plasticized cellulosic materials, polyurethanes, and polyamides.

64. (Previously Presented) The device of claim 61, further comprising a movable member within the impermeable reservoir separating the active agent from a swellable agent.

65. (Currently Amended) An implantable LHRH agonist delivery system comprising:

an impermeable reservoir;

a water-swellable agent formulation within the reservoir;

an LHRH agonist within the reservoir;

a semipermeable material arranged to allow fluid to pass into the water-swellable agent; and

a back-diffusion regulating outlet arranged to allow the LHRH agonist to be delivered from the reservoir at a desired flow rate, wherein the system effectively isolates the LHRH agent from a surrounding environment of use, and wherein the reservoir and the back-diffusion regulating outlet having surfaces in a mating relationship and ~~has~~ a helical flow path formed between the mating surfaces.

66. (Previously Presented) The system of claim 65, wherein the system achieves at least approximately 70% steady-state delivery on or before 14 days and continues this rate for at least one year.

67. (Previously Presented) The system of claim 65, wherein the LHRH agent is effectively isolated from the environment of use for at least two months.

68. (Previously Presented) The system of claim 65, wherein the LHRH agonist is leuprolide acetate.

69. (Previously Presented) The device of claim 51, wherein the helical flow path has a diameter of about 0.003 to about 0.020 inches.

70. (Currently Amended) The device of claim 52, wherein the back diffusion regulating outlet comprises a thermoplastic member and the reservoir comprises a metal capsule and the helical flow path is formed by a helical groove in an exterior of ~~a~~ the thermoplastic member and by an interior of ~~a~~ the metal capsule.

71. (Currently Amended) A fluid-imbibing device for delivering an active gent to a fluid environment of use, said device comprising a water-swellable semipermeable material that is received in sealing relationship with an interior surface of an open end of an implantable reservoir, a back diffusion regulating outlet ~~having a helical flow path~~, and an active agent to be displaced from the device when the water-sweallable material swells, wherein the semipermeable material is a substantially cylindrical plug which expands radially upon hydration to provide a friction fit and expands longitudinally to displace the active agent, wherein the implantable reservoir and the back diffusion regulating outlet have surfaces in a mating relationship and a helical flow path formed between the mating surfaces.

72. (Previously Presented) The device of claim 71, wherein the semipermeable material seals to the interior surface of the open end such that the semipermeable material is retained in the open end.

73. (Currently Amended) The device of claim 55, wherein ~~the semipermeable material seals provide~~ there is a clearance between the circumferential ridges and an interior surface of the reservoir into which the semipermeable material expands due to hydration.

74. (Canceled)

75. (Previously Presented) The device of claim 71, wherein the semipermeable material is selected from the group consisting of plasticized cellulosic materials, polyurethanes, and polyamides.

REMARKS/ARGUMENTS

Favorable reconsideration of this application is requested in view of the amendments above and the remarks which follow.

DISPOSITION OF CLAIMS

Claims 51-73 and 75 are pending in this application. Claim 74 has been canceled its features are recited in claim 71. The pending claims have been amended as set forth above to clarify what the applicant regards as the invention and to improve their readability. In independent claims 51, 52, 65, and 71, support for the reservoir and back diffusion regulating outlet having surfaces in a mating relationship, wherein a helical flow path is formed between the mating surfaces, can be found throughout the specification, for example, at page 6, line 24 to page 7, line 14. The term "semipermeable plug" has been used in place of "semipermeable material" in independent claim 55 to clarify what the applicant regards as the invention. Support for the term "semipermeable plug" can be found throughout the specification, for example, at page 6, lines 29-30. In claims 55, 61, and 73, the location of the circumferential ridges has been clarified.

REJECTIONS UNDER 35 U.S.C. §103

Claims 51-75 were rejected under 35 U.S.C. 103(a) as being unpatentable over Laby et al. (U.S. Patent No. 4623330) in view of Portner et al. (U.S. Patent No. 4360019), Magruder et al. (U.S. Patent No. 5238687), and further in view of Mia (U.S. Patent 5519002). Claim 74 has been canceled. Accordingly, the rejection of claim 74 is moot. Reconsideration of the rejection of claims 51-73 and 75 is respectfully requested.

Claims 51, 52, 53, 54, 57, 58, 65-72, and 75

Laby et al., Portner et al., Magruder et al., and Mia, in combination, do not disclose or teach an implantable or fluid-imbibing device in which a reservoir and a back diffusion regulating outlet have surfaces in a mating relationship, wherein a helical flow path is formed between the mating surfaces, as recited in claims 51, 52, 53, 54, 57, 58, 65-72, and 75.

Withdrawal of the rejection of claims 51, 52, 53, 54, 57, 58, 65-72, and 75 over the combination of these references is respectfully requested.

The Examiner has suggested that a helical spring can be used to regulate back diffusion in view of Portner et al. However, a helical spring by itself will not regulate back diffusion because fluid will be able to move freely through the through-bore defined by the helical spring. In Portner et al., a helical spring bears against a valve body (41) in order to close an inlet port (35) between a tube (34), extending into a reservoir (26), and an appendage (42) of a pumping chamber (28). The inlet port (35) is normally closed unless the pressure acting on the valve body from the reservoir (26) is sufficient to overcome the force of the spring bearing against the valve body. When the force of the spring is overcome, the valve body moves away from the inlet port, thereby allowing fluid to escape from the reservoir. The spring, as used in Portner et al., does not define a helical flow path between the valve body and the reservoir. Moreover, the Portner et al. system requires a pumping device to pressurize the fluid in the reservoir in order to overcome the force of the spring. In the instant application, the helical flow path remains open and naturally regulates back diffusion so that a separate pumping device is not needed to deliver fluid from the reservoir.

Claims 55, 56, 59, 60, 61-64, and 73

Laby et al., Portner et al., Magruder et al., and Mia, in combination, do not disclose or teach an implantable or fluid-imbibing device having a semipermeable plug that is received in sealing relationship with an interior surface of a reservoir and wherein an exterior surface of the semipermeable plug has circumferential ridges, as recited in claims 55, 56, 59, 60, 61-64, and 73. Withdrawal of the rejection of claims 55, 56, 59, 60, 61-64, and 73 over the combination of these references is respectfully requested.

Magruder discloses a protective sleeve for placement at a distal end of the reservoir. This distal end contains an osmotic agent and can expand. The protective sleeve is used to contain the expansion of the distal end of the reservoir. The protective sleeve, being a sleeve, has a through-bore. The membrane referenced in claim 28 of Portner et al. refers to a releasable septum (58) inserted in an opening (54) (col. 5, lines 19-23). There is a valve (56) in the opening (54). When drug is injected into the opening (54) through the septum (58), the valve (56) opens in response to fluid pressure, thereby allowing fluid to flow into the reservoir.

The Examiner has suggested that because Magruder makes the protective sleeve from a semipermeable material, it would be obvious to make the releasable septum from a semipermeable material. However, these elements, releasable septum and protective sleeve, are materially different in function and it is not obvious at all that what applies to the releasable septum also applies to the protective sleeve. Moreover, making the releasable septum from a semipermeable material would not disclose or teach a semipermeable plug having an exterior surface with circumferential ridges, as recited in claims 55, 56, 59, 60, 61-64, and 73. Perhaps the Examiner is considering replacing the releasable septum with the protective sleeve. However, if the releasable septum is replaced with the protective sleeve, the check valve (56) would be open always, without the protection of the releasable septum. In a fluid environment, fluid would constantly enter the reservoir, contaminating the drug in the reservoir. Further, replacing the releasable septum with the protective sleeve would not disclose or teach a semipermeable plug having an exterior surface with circumferential ridges, as recited in claims 55, 56, 59, 60, 61-64, and 73.

CONCLUSION

Applicant believes that this paper is fully responsive to the Office Action dated June 14, 2007, and respectfully requests that a timely Notice of Allowance be issued in this case. A call to the undersigned is encouraged if the Examiner believes that a telephone conference would advance prosecution of this application.

Please apply any charges not covered or credits in connection with this filing to Deposit Account No. 503202 (ref. ARC2437USCON6).

Respectfully submitted,

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